AIN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
1:25-cv-00368

United Therapeutics Corporation,

Plaintiff,

v.

Liquidia Technologies, Inc.,

Defendant.

ORAL ARGUMENT REQUESTED

MEMORANDUM IN SUPPORT OF DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S MOTION TO DISMISS OR, IN THE ALTERNATIVE, STAY OR TRANSFER

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

STATEMENT OF THE NATURE OF THE MATTER

This is Plaintiff United Therapeutics Corporation's third patent lawsuit seeking to enjoin its future competitor, Defendant Liquidia Technologies, Inc., from bringing a life-saving drug to the market. Because all issues raised here were fully litigated, could have been litigated, or are currently pending, principles of comity, economy, efficiency, and preclusion urge dismissal. In the alternative, this case should be stayed pending resolution of UTC's ongoing litigation or transferred to the U.S. District Court for the District of Delaware.

INTRODUCTION

This case is the latest of many failed attempts by UTC to use litigation to prevent Liquidia from marketing a life-saving drug, Yutrepia. After an initial failed federal Hatch-Waxman litigation filed nearly five years ago in the District of Delaware, two failed Administrative Procedure Act litigations against the FDA in the District of Columbia, two pending North Carolina state-court actions, and on the eve of trial in a second Hatch-Waxman suit in Delaware, UTC now brings its seventh case—which is the *third* one to raise the *same* issues against the *same* defendant in connection with the *same* allegedly infringing product.

Liquidia requests that this Court exercise its discretion under the first-filed rule, which instructs courts facing similar lawsuits in different federal courts to prioritize the first-filed suit to promote the interests of comity, economy, and efficiency. And, because UTC alleges nothing here that could not have been included in the pending Delaware action

and, thus, has engaged in impermissible claim-splitting, Liquidia requests that this Court dismiss this action. In the alternative, Liquidia requests that the Court stay the case pending resolution of the first-filed Delaware action, which is set for trial at the end of June, or transfer it to the District of Delaware, where UTC has been bringing virtually identical claims since 2020.

Should the Court decline to exercise its discretion under the first-filed rule, Liquidia moves to dismiss this case under several preclusion doctrines. This litigation raises issues that were, or could have been, brought in the Hatch-Waxman litigations. Thus, the doctrines of issue preclusion, claim preclusion, and the Federal Circuit's *Kessler* doctrine all bar UTC's attempt for yet another bite at the apple.

BACKGROUND

The parties are biotechnology companies that, among other things, research and develop treatments for certain pulmonary diseases. DE 1, ¶¶ 1, 3, 21. This includes drugs to treat the chronic conditions of pulmonary hypertension ("PH"), which includes pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD").

Since January 2020, Liquidia has sought approval from the FDA for the manufacture, use, and sale of its proposed Yutrepia product to treat PAH and PH-ILD by delivering the drug treprostinil through a dry powder inhaler. Since June 2020, however, UTC has brought a series of lawsuits seeking to prevent Yutrepia from entering the market, including this one.

A. UTC brings multiple suits in the District of Delaware relating to its patents for drugs treating PH.

1. The first Hatch-Waxman case and related litigation.

In June 2020, UTC initiated its first Hatch-Waxman patent litigation against Liquidia in the District of Delaware. *See generally United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 1:20-cv-00755-RGA (D. Del.) ("*Hatch-Waxman I*").[1] Originally, UTC premised its case on two patents, U.S. Patent Nos. 9,593,066 ("the '066 Patent") and 9,604,901 ("the '901 Patent").[2]

About a month later, on July 21, 2020, UTC obtained a new patent, U.S. Patent No. 10,716,793 ("the '793 Patent"), directed at a method of treating PH. *See* Exhibit A. A day later, UTC amended its complaint in *Hatch-Waxman I* to add the '793 Patent to the case.[3]

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[1] Filings in other federal courts are matters of public record that this Court may consider on a motion to dismiss. *See Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 557 (4th Cir. 2013); *see also Hill v. Carvana, LLC*, No. 1-22-CV-37, 2022 WL 1625020, at *3 (M.D.N.C. May 23, 2022) (explaining that "Federal Rule of Evidence 201 allows a court to take judicial notice of a document filed in another court to establish the fact of such litigation") (citation omitted).

[2] The '901 Patent was found invalid by the Patent Trial and Appeal Board ("PTAB"), and the Delaware court granted UTC's stipulation of noninfringement in January 2022. *Hatch-Waxman I*, DE 278.

[3] In June 2021, UTC sought to amend again to include claims relating to allegations of trade secret misappropriation and to add a new defendant, Dr. Robert Roscigno, who, at varying times, was employed by both UTC and Liquidia. *Hatch-Waxman I*, DE 109. The Delaware court denied the motion to amend, and UTC filed suit in North Carolina state court in December 2021. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 21-CVS-4094 (N.C. Super. Ct. Durham Cnty.). That case remains pending in the North Carolina Business Court, along with a breach of contract case filed in May 2024. *See United Therapeutics Corp. v. Roscigno*, No. 24-CVS-3755 (N.C. Super. Ct. Durham Cnty.).

Hatch-Waxman I, DE 16.[4] Claim 1 of the '793 Patent is a "method of treating pulmonary hypertension" administered "by inhalation" with a dose containing 15-90 micrograms of "treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths[,]" while claim 4 requires "the inhalation device is a dry powder inhaler." Ex. A at 18:23-31, 18:36-37.

A bench trial was held in March 2022. In August 2022, the Delaware court issued a split decision, holding that Liquidia did not infringe any valid claims of the '066 Patent, but that the '793 Patent was valid and infringed. *See generally United Therapeutics Corp. v. Liquidia Techs, Inc.*, 624 F. Supp. 3d 436 (D. Del. 2022). That decision was affirmed by the Federal Circuit in July 2023. *See generally United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360 (Fed. Cir. 2023).

Between the March 2022 bench trial and the court's August 2022 decision, however, the PTAB held in a parallel proceeding that all the claims of the '793 Patent claims were invalid. The Federal Circuit affirmed in December 2023. *See United Therapeutics Corp. v. Liquidia Techs, Inc.*, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023). Liquidia moved under Rule 60(b) for the Delaware court to amend its judgment, which was granted in March 2024, thereby entering judgment of non-infringement of the '793 Patent in favor of

[4] The Court can consider the '793 Patent because it was an exhibit to the complaint in UTC's second Delaware case. In addition, the Court may take judicial notice of UTC's patents, as they are publicly available on the United States Patent and Trademark Office's website and thus a source whose accuracy cannot be reasonably questioned. *See, e.g., Foster Poultry Farms v. Alkar-Rapidpak-MP Equip., Inc.*, 868 F. Supp. 2d 983, 990 (E.D. Cal. 2012) (collecting cases).

Liquidia based on that patent's invalidity. *Hatch-Waxman I*, DE 462 (Rule 60(b) motion); *id.*, DE 480 at 3 (amended judgment).

2. The pending Hatch-Waxman case.

In July 2023, Liquidia notified UTC that it amended its NDA to add PH-ILD as an indication for Yutrepia. Soon after, in September 2023, UTC filed its second patent infringement case, again alleging infringement of the previously litigated '793 Patent, based on Liquidia's amended FDA application to add the PH-ILD indication. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 1:23-cv-00975-RGA (D. Del.) ("*Hatch-Waxman II*"), DE 1.

Later that year, in November 2023, UTC obtained another patent, Patent No. 11,826,327 ("the '327 Patent"), which is directed at a specific method of treating PH-ILD, rather than the '793 Patent's broader claims covering both PAH and PH-ILD. A few days later, UTC amended the *Hatch-Waxman II* complaint to include claims based on the '327 Patent. *Hatch-Waxman II*, DE 8.

In January 2024, the parties stipulated to the dismissal of UTC's '793 Patent infringement claims in *Hatch-Waxman II* based on the Federal Circuit's affirmance of the PTAB's invalidity determination. *Hatch-Waxman II*, DE 17. Although that dismissal was without prejudice, the parties stipulated that UTC would be permitted to amend the *Hatch-Waxman II* complaint to reinsert the '793 Patent only if the Federal Circuit's decision were vacated or reversed. *Id.* Neither happened.[5] Thus, any issues in *Hatch-Waxman II* about

[5] *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 2023-1805, DE 63 (Fed. Cir.

the ’793 Patent are final.

Hatch-Waxman II proceeded on the ’327 Patent claims. In February 2024, UTC moved for a preliminary injunction, seeking to enjoin Liquidia from launching Yutrepia for the PH-ILD indication. *Hatch-Waxman II*, DE 33 at 1; DE 69. In May 2024, the Delaware court denied the motion, holding that (1) there is a substantial question about the ’327 Patent’s validity, (2) UTC is unlikely to suffer irreparable harm absent an injunction, and (3) the public interest weighs against an injunction. *See generally Hatch-Waxman II*, 2024 WL 2805082 (D. Del. May 31, 2024).[6]

A bench trial is currently scheduled to begin on June 23, 2025. *Hatch-Waxman II*, DE 45.[7]

Mar. 12, 2024) (order denying UTC petitions for panel rehearing and rehearing en banc); *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 145 S. Ct. 352 (Mem.) (2024) (opinion denying petition for writ of certiorari).

[6] UTC has filed a motion for a TRO and preliminary injunction here, based on the same allegations of irreparable harm already considered and denied by the District of Delaware. *See* DE 3.

[7] UTC also brought APA claims against the FDA in two cases alleging that the FDA improperly permitted Liquidia to file an amendment to its New Drug Application (“NDA”) to add the PH-ILD indication in July 2023, and instead should have required Liquidia to file a new NDA. *See United Therapeutics Corp. v. FDA*, No. 1:24-cv-00484 (D.D.C.) (“*APA I*”); *Liquidia Techs., Inc. v. FDA*, No. 1:24-cv-02428 (D.D.C.), DE 30 (“*APA II*”). In August 2024, after briefing on the FDA’s and Liquidia’s motions to dismiss was completed, UTC voluntarily dismissed *APA I*. *APA I*, DE 56. And on May 2, 2025, the court in *APA II* granted the FDA’s and Liquidia’s motions to dismiss UTC’s cross-claims. *APA II*, DE 103. In both cases, the courts denied UTC’s requests for a TRO and preliminary injunction. *APA I* (March 29, 2024 Minute Entry denying UTC’s motion for TRO and motion for preliminary injunction); *APA II*, DE 103 (denying as moot UTC’s TRO and preliminary injunction motion).

B. UTC files patent infringement complaint in this Court based on the same issues raised in its previous cases.

1. UTC obtains the '782 Patent in June 2022.

In June 2022—four months before the Delaware court issued its first ruling in *Hatch-Waxman I*, one month before the PTAB invalidated the '793 Patent, and a year before UTC filed suit in *Hatch-Waxman II*—UTC obtained U.S. Patent No. 11,357,782 ("the '782 Patent"). DE 1, ¶ 17; *see also* DE 1-1, Ex. A ('782 Patent).

The specification of the '782 Patent is from the same patent family as the invalid '793 Patent and shares identical disclosures. *Compare* DE 1-1('782 Patent) at 1:1-19:16, *with* Ex. A ('793 Patent) at 1:1-18:46. The claims, too, are extremely similar. Like claim 1 of the '793 Patent, claim 1 of the '782 Patent is directed to a "method of treating pulmonary hypertension" through an "inhalation device" with a dose containing 15-90 micrograms of "treprostinil or a pharmaceutically acceptable salt thereof" that is delivered "in 1 to 3 breaths[.]" DE 1-1, cl. 1. And just like claim 4 of the '793 Patent, the delivery device in the '782 Patent is a dry powder inhaler. *Id.* A chart comparing relevant claims from the patents is attached as Appendix A.

UTC did not assert the '782 Patent in the *Hatch-Waxman II* suit, even though the case was originally premised on the alleged infringement of the nearly identical '793 Patent and exactly the same product, Yutrepia. Indeed, UTC did not even list the '782 Patent in the FDA's "Orange Book"[8] until just a few weeks ago, April 24, 2025, well past the 30-

[8] *See* Exhibit B (Tyvaso DPI Orange Book), available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=214324&Appl_type=N.

day deadline to list an issued patent. *See* 21 U.S.C. § 355(c)(2); *see also* 21 C.F.R. § 314.53(d)(3).

2. UTC files this suit.

On May 9, 2025—one week after the District of Columbia dismissed UTC's *APA II* case on May 2, 2025, and denied it a preliminary injunction—UTC filed its belated complaint in this Court. Although UTC purports to base the alleged infringement on an amended version of the Yutrepia NDA and label filed with the FDA in November 2024 (six months ago), the infringing product is no different than that alleged in the two previous Delaware actions. DE 1, ¶¶ 19–29. As shown below, there is nothing materially relevant to the '782 Patent in Liquidia's amended NDA such that UTC could not have filed suit based on the NDA prior to the amendment. The allegations in Delaware and here hinge on Liquidia's efforts to seek FDA approval to engage in the manufacture, use, and sale of Yutrepia and allege that use of Yutrepia and its dry powder inhaler, infringe UTC's patents for a treprostinil-based dry inhalation powder for the treatment of PAH and PH-ILD. *Compare*, *e.g.*, DE 1, ¶¶ 39, 41, *with Hatch-Waxman II*, DE 8, ¶¶ 13, 25–26, 29, 39.

This case is based on the same Yutrepia product that was actually litigated, in *Hatch-Waxman I* and is currently being litigated in *Hatch-Waxman II*. The allegations of infringement raised here were known to UTC since *at least* the March 2022 trial in *Hatch-Waxman I*:

- Yutrepia comprises "an inhalation dry powder formulation with an active ingredient treprostinil indicated for the treatment of pulmonary

hypertension" (DE 1, ¶ 41; *compare id. with Hatch-Waxman I*, 624 F. Supp. 3d at 443 *and* Exhibit C at 4–5[9].

- "Liquidia promotes, suggests, and instructs the use of Yutrepia™ in dosages of at least 15 mcg to 90 mcg per treatment session over one to three breaths" (DE 1, ¶ 42; *compare id. with Hatch-Waxman I*, 624 F. Supp. 3d at 460 and Ex. C at 4–5).

- "[P]atients that are prescribed Yutrepia will use an accompanying inhalation device to administer a dosage of treprostinil in capsule strengths ranging from 26.5 mcg to 106 mcg over one to two breaths resulting in a dose delivered of 15.1 mcg to 75.7 mcg of treprostinil." (DE 1, ¶ 43; *compare id. with Hatch-Waxman I*, 624 F. Supp. 3d at 460 *and* Ex. C at 4–5).

- "Liquidia promotes, suggests, and instructs the administration of Yutrepia in less than five minutes" and that "the Instructions for Use disclose that each Yutrepia capsule 'must be inhaled within 5 minutes.'" (DE 1, ¶ 44; *compare id. with* Ex. C at 18).

- Yutrepia's "[p]rescribing Information also discloses a minimum recommended dosing interval of four hours." (DE 1, ¶ 45; *compare id*. with Ex. C at 4–5 (recommending, among other things, dosage of 3 to 5 times per day).

Nor is there any difference on these issues between Exhibit C—Yutrepia's 2021 Label and Instructions for Use (available publicly in the March 2022 *Hatch-Waxman I*)—and the revised version from 2024 that UTC attached as Exhibit B to its complaint. The images UTC identifies in its complaint are identical between the two versions of the instructions. *See* Appendix B (*comparing* DE 1, ¶¶ 25, 29 *with* Ex. C at 23, 18).

Indeed, the only material difference between the cases appears to be Liquidia's recent announcement of the FDA's potential approval of Liquidia's new drug application

[9] Exhibit C was a trial exhibit in the *Hatch-Waxman I* trial and includes Yutrepia's 2021 label and instructions for use. *See Hatch-Waxman I*, DE 395 at 10 (trial exhibit DTX408).

(DE 1, ¶¶ 31–33)—but UTC already knew and expected that as well, having unsuccessfully requested a preliminary injunction in *Hatch-Waxman II*, *APA I*, and *APA II* based on FDA's potential approval. *See generally Hatch-Waxman II*, 2024 WL 2805082.

STATEMENT OF THE QUESTION PRESENTED

1. Whether the Court should dismiss, stay, or transfer this case in favor of the pending first-filed federal litigation in the District of Delaware.

2. Whether UTC's claims, which involve issues that have been or should have been fully litigated in the prior Delaware litigations, are precluded under the doctrines of claim preclusion, issue preclusion, and the Federal Circuit's *Kessler* doctrine.

ARGUMENT

Under the first-filed rule and because UTC has engaged in impermissible claim splitting between this Court and the pending case in the District of Delaware, this case should be dismissed. In the alternative, the case should be stayed pending resolution of the Delaware case or transferred to the District of Delaware which is already intimately familiar with UTC's patents and Liquidia's Yutrepia product.

Should the Court reach the merits, this case should be dismissed under Rule 12(b)(6) because it is clear from the face of the complaint and from documents of which this Court may take judicial notice that multiple preclusion doctrines prohibit UTC from engaging in serial litigation of the same claims.

I. The Court should exercise its equitable discretion under the first-filed rule to dismiss this case or, in the alternative, stay or transfer it in favor of the pending Delaware litigation.

The first-filed rule applies here. The parties are identical, and UTC raises no issues here that could not have been raised in the pending *Hatch-Waxman II* case. Because UTC has engaged in impermissible claim-splitting, Liquidia asks the Court to exercise its discretion to dismiss the case. In the alternative, Liquidia requests that the Court either (1) stay this litigation until the pending Delaware action is resolved by the bench trial currently set for June, or (2) transfer the case to Delaware.

A. The first-filed rule bars UTC from filing claims based on the same underlying facts in multiple federal fora.

Where, as here, "a lawsuit is filed in multiple forums," "the first suit should have priority[.]" *Davis v. Zuccarello*, No. 1:16-CV-01086, 2017 WL 2729089, at *2 (M.D.N.C. June 23, 2017) (citations omitted). This rule, called the "first-filed" or "first-to-file" rule, is grounded in "doctrines of federal comity[,]" and its application is an "equitable determination" made at the court's discretion. *Nutrition & Fitness, Inc. v. Blue Stuff, Inc.*, 264 F. Supp. 2d 357, 360 (W.D.N.C. 2003) (citing cases).

Courts use "a three-factor test for determining whether multiple cases are subject to the first-to-file rule, considering (1) the chronology of the filings, (2) the similarity of the parties involved, and (3) the similarity of the issues being raised." *Davis*, 2017 WL 2729089, at *2-3. When the rule applies, a court has discretion to dismiss, stay, or transfer the later-filed case. *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012) (listing

options).[10] Factors (1) and (2) are easily satisfied here, as both *Hatch-Waxman I* and *Hatch-Waxman II* preceded this case and the parties in all three suits are identical. In addition, as explained above, UTC cannot legitimately dispute the issues in all three suits—whether Yutrepia infringes UTC's patents directed to the treatment of PH, including PAH and PH-ILD, using treprostinil-based dry-powder inhaled device—are similar, if not identical. *See supra* Background § B.2.

Nor does it matter that this case involves a different patent than the one currently at issue in Delaware. As preliminary matter, *Hatch-Waxman II* originally concerned the '793 Patent, which is nearly identical to the '782 Patent. If UTC believed that Yutrepia infringed the '793 Patent, there would be no reason for UTC to think that the product does not also infringe the '782 Patent. And, of course, had the '782 Patent been put at issue in *Hatch-Waxman II*, Liquidia would have raised before the Delaware court the same validity questions that plagued the (since-dismissed) invalid '793 Patent, because the '782 Patent was allowed and issued *before* the PTAB invalidated the '793 Patent. In that proceeding, the PTAB rejected the same arguments UTC made to obtain allowance of the '782 Patent in the first place.

In any case, the first-filed rule "does not require that the actions being assessed be

[10] The Federal Circuit has held that, where, as here, the question of whether a second-filed action should proceed is "sufficiently tied to patent law[,]" that decision is "governed by" Federal Circuit law. *Futurewei Techs., Inc. v. Acacia Rsch. Corp.*, 737 F.3d 704, 708 (Fed. Cir. 2013). That said, Liquidia is unaware of any material difference between the Federal and Fourth Circuits' application of the first-to-file rule.

identical if there is substantial overlap with respect to the issues and the parties." *Gonzalez v. Homefix Custom Remodeling, Corp.*, 670 F. Supp. 3d 337, 343 (E.D. Va. 2023) (cleaned up). For example, even if actions "involve different legal and factual issues," they are substantially similar under the rule if, as here, they "involve the same ongoing dispute between the same parties," "both seek injunctive relief" under the same statute, and "both will rely on some of the same evidence." *US Airways, Inc. v. US Airline Pilots Ass'n*, No. 3:11-cv-371-RJC-DCK, 2011 WL 3627698, at *2 (W.D.N.C. Aug. 17, 2011).

This is the same dispute, between the same parties, over the same product, for the same relief, and based on the same evidence. The first-filed rule applies.

B. Because UTC has engaged in impermissible claim splitting, the Court should dismiss the case.

This Court should dismiss this case because UTC has violated the rule against claim splitting, prohibiting "a plaintiff from prosecuting its case piecemeal and requires that all claims arising out of a single wrong be presented in one action." *Sensormatic Sec. Corp. v. Sensormatic Elecs. Corp.*, 273 F. App'x 256, 265 (4th Cir. 2008) (citation omitted). Thus, "[t]he claim-splitting doctrine, like *res judicata*, bars a second suit, if the claim in such suit involves the same parties . . . and arises out of the same transaction or series of transactions as the claims in the first suit." *Superior Performers, Inc. v. Fam. First Life, LLC*, No. 1:14-CV-382, 2015 WL 471389, at *3 (M.D.N.C. Feb. 4, 2015) (cleaned up).

Claim-splitting differs from *res judicata* in that it "bars two suits that are pending at the same time, while *res judicata* bars a second suit that is filed after the final adjudication of a first suit." *Id.* at *4. The principle behind the claim-splitting rule is simple: "When

one suit is pending in federal court, a plaintiff has no right to assert another action on the same subject . . ., against the same defendant[,] at the same time." *Sensormatic*, 273 F. App'x at 265 (cleaned up). Courts thus dismiss suits under claim-splitting principles to avoid "put[ting] the parties to the cost and vexation of multiple lawsuits, deplet[ing] judicial resources, foster[ing] inconsistent decision[s], and diminish[ing] reliance on judicial decisions." *Sensormatic Sec. Corp. v. Sensormatic Elecs. Corp.*, 452 F. Supp. 2d 621, 628 (D. Md. 2006) (cleaned up).

Here, the parties are identical and both cases concern the same transaction—whether use of Yutrepia for the treatment of PAH and PH-ILD, infringes UTC's patents for a treprostinil-based dry-powder inhaled device. *Compare* DE 1, ¶¶ 50–53, *with Hatch-Waxman II*, DE 8, ¶¶ 3, 25–27. At this point, allowing UTC to extend the life of the dispute with duplicative litigation—whether here or in Delaware—violates all of the principles animating the rule against claim-splitting.

And, again, it is of no matter that this case involves a different patent. As with *res judicata*, the rule against claim splitting bars claims that "could have been" brought in the original action. *Taylor v. Norfolk S. Ry., Co.*, 86 F. Supp. 3d 448, 456 (M.D.N.C. 2015). To hold otherwise "would allow parties to frustrate the goals of *res judicata* through artful pleading and claim splitting given that a single cause of action can manifest itself into an outpouring of different claims, based variously on federal statutes, state statutes, and the common law." *Id.* (cleaned up). Because UTC could have asserted a claim based on alleged infringement of the '782 Patent in *Hatch-Waxman II*, the rule against claim splitting

bars it from doing so here.

Accordingly, the Court should dismiss this action.

C. In the alternative, the Court should either stay the case pending resolution of the pending Delaware action or transfer this case to the District of Delaware.

If the Court does not dismiss this action, then, alternatively and for the reasons discussed above concerning first-to-file and claim splitting, the Court should stay it until *Hatch-Waxman II* concludes, or transfer it to the District of Delaware. The bench trial in *Hatch-Waxman II* is a little over a month away and principles of comity, efficiency, and economy would all be served by staying this litigation at least until *Hatch-Waxman II* is resolved.

At the very least, this case should be transferred to the Delaware court. Transfer is appropriate when the district with the earlier-filed case would provide "a broader and more comprehensive forum for resolving the entire dispute between the parties." *First Nationwide Mortg. Corp. v. FISI Madison, LLC*, 219 F. Supp. 2d 669, 674 (D. Md. 2002). The District of Delaware would provide that broader and more comprehensive forum for this dispute, as that district has already presided over a case involving Yutrepia and UTC's patents all the way to final judgment, with another case pending. Nor do any of the factors under 28 U.S.C. § 1404 suggest that the interests of justice would be better served by allowing this case to remain here, rather than the court where these same parties have been litigating identical issues for the last five years. Indeed, a transfer would promote judicial efficiency, as the court in the District of Delaware is well-acquainted with the parties and

UTC's infringement theories.[11]

Thus, under the first-filed rule, this Court should dismiss this action or, in the alternative, stay or transfer it.

II. UTC's claims are precluded by issue preclusion, claim preclusion, and the Federal Circuit's *Kessler* doctrine.

Should the Court decline to dispose of this action under the procedural first-filed rule, Liquidia asks that the Court dismiss it as substantively precluded by the final judgment in *Hatch-Waxman I* and the dismissal, with finality, of the claims concerning the '793 Patent in *Hatch-Waxman II*.

A. UTC's claims are barred by claim preclusion (*res judicata*).

"In its simplest construct, *res judicata* precludes the relitigation of a claim, or cause of action, or any possible defense to the cause of action which is ended by a judgment of the court." *Nystrom v. Trex Co.*, 580 F.3d 1281, 1284–85 (Fed. Cir. 2009) (citation omitted). "For claim preclusion in a patent case, an accused infringer must show that the *accused product* . . . in the second suit is essentially the same as the *accused product* . . . in the first suit." *Id.* (emphasis added) (cleaned up). "Colorable changes in an infringing device or changes unrelated to the limitations in the claim of the patent would not present a new cause of action." *Id.* (citation omitted).

[11] It doesn't matter that UTC filed this case as a related case to *Liquidia Techs., Inc. v. United Therapeutics Corp.*, C.A. 1:25-cv-00299 (M.D.N.C.). DE 1, ¶ 9 n.1. That case involves *Liquidia's* assertions that *UTC's* product infringes *Liquidia's* patent. As such, the case will raise *different* facts about the application of a *different* patent to a *different* product. There is no reason to believe that the facts or issues raised here will overlap with those at issue in Liquidia's lawsuit.

Here, UTC seeks to relitigate matters ended by the final judgment in *Hatch-Waxman I*. That is, UTC is seeking to bring an infringement claim on the same product—Yutrepia—administered the same way through the same device. UTC's complaint identifies no aspects of Liquidia's product — not its device, not its dosage, not its administration—that differs in any way than allegations that were adjudicated to finality in the first litigation. Thus, "[i]n essence," UTC would be attempting here "to prove infringement of the same claim limitations as to the same features of the accused devices." *Nystrom*, 580 F.3d at 1285–86. "As such, this case presents the exact situation that *res judicata* seeks to prevent[,]" and "[*r*]*es judicata* thus bars this second attempt to adjudicate the same issues." *Id.* at 1286.

Hatch-Waxman II also bars any claim here. There, UTC voluntarily dismissed its claims for infringement of the '793 Patent, which covers both PAH and PH-ILD. It cannot raise them again because the '793 Patent's invalidity and non-infringement have been affirmed to finality.

In addition, when determining whether a claim arises out of the same transactional facts as those alleged in an earlier suit in patent cases, the Federal Circuit has instructed courts look to "*both* the asserted patents and the accused activity."[12] *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1165 (Fed. Cir. 2018) (emphasis added). Thus, even if the

[12] While regional circuit law governs general preclusion questions, Federal Circuit law governs the particular question of whether a patent cause of action arises out of the same transactional facts. *SimpleAir*, 884 F.3d at 1165.

asserted patents differ between cases, claim preclusion still applies "if the scope of the asserted patent claims in the two suits is essentially the same." *Id.* at 1167. And here, not only is the accused product and conduct identical, the scope of the two asserted patents here and in Delaware—the virtually identical '793 and '782 Patents—are the same. *See* Appendix A.

In the words of the Federal Circuit, "[a]t its core," what UTC seeks here is "a second"—indeed, a third—"bite at the apple, to assert its patent against the same party, [Liquidia], and the same product, [Yutrepia]." *Senju Pharm. Co. v. Apotex Inc.*, 746 F.3d 1344, 1353 (Fed. Cir. 2014). "But that is exactly what claim preclusion was designed to prevent." *Id.* This Court should protect Liquidia from "repetitious suits involving the same cause of action" and hold that *res judicata* bars UTC's claims. *Id.* (citation omitted).

B. UTC's claims are barred by issue preclusion (collateral estoppel).

Collateral estoppel (or issue preclusion) "forecloses the relitigation of issues of fact or law that are identical to issues which have been actually determined and necessarily decided in prior litigation in which the party against whom issue preclusion is asserted had a full and fair opportunity to litigate.'" *Allergan, Inc. v. Apotex, Inc.*, No. 1:14-CV-1028, 2015 WL 13358250, at *2 (M.D.N.C. Aug. 31, 2015), *aff'd sub nom. Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955 (Fed. Cir. 2017) (cleaned up). The proponent of collateral estoppel must establish that: "(1) the issue sought to be precluded is identical to one previously litigated; (2) the issue [was] actually determined in the prior proceeding; (3) determination of the issue [was] a critical and necessary part of the decision in the prior

proceeding; (4) the prior judgment [is] final and valid; and (5) the party against whom the estoppel is asserted ... had a full and fair opportunity to litigate the issue in the previous forum." *Id.* (quoting *Sedlack v. Braswell Servs. Grp., Inc.*, 134 F.3d 219, 224 (4th Cir. 1998)).

Here, the litigation of issues in *Hatch-Waxman I* and *II* estops UTC from relitigating them here. Those actions turned on the '793 Patent, gave UTC a full and fair opportunity to litigate, and resulted in a final judgment on those claims. The only question for this Court is whether the '793 allegations about Yutrepia match the allegations here. They do. That is, UTC litigated the issue of Yutrepia's alleged infringement of the '793 Patent to final judgment and an amended judgment in *Hatch-Waxman I* and dismissal in *Hatch-Waxman II*. As explained, this included UTC's identical allegations of infringement involving device, dosage, and administration of Yutrepia™. *See, e.g.*, *Hatch-Waxman I*, 624 F. Supp. 3d at 460–62 (addressing UTC's infringement arguments).

Moreover, in patent law, issue preclusion may apply even if the patent claims are not identical. *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013); *see also In re PersonalWeb Techs. LLC*, 961 F.3d 1365, 1374 (Fed. Cir. 2020) ("Claim preclusion bars both those claims that were brought as well as those that could have been brought in the earlier lawsuit."). "Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply." *Ohio Willow Wood*, 735 F.3d at 1342. "If the differences between the unadjudicated patent claims and the adjudicated patent claims do not materially alter the question of invalidity, collateral

estoppel applies." *Id.* "The mere use of different words in the unadjudicated claims does not necessarily create a new issue of invalidity[,]" and "courts examine whether the asserted claims are 'substantially similar' to the invalidated claims, and whether any differences in the asserted claims are 'patentably significant' in a way that 'changes the invalidity analysis.'" *Allergan*, 2015 WL 13358250, at *2 (quoting *Ohio Willow Wood*, 735 F.3d at 1342–43).

Allergan shows the proper analysis. There the plaintiff filed serial patent infringement lawsuits. *Id.* at *1. In the first cases the defendant prevailed upon findings that four patents were invalid. *Id.* In the last suit, the plaintiff launched another assault based on a fifth patent. *Id.* The plaintiff attempted to distinguish the cases, arguing that the first four patents all concerned the "growth of eyelashes[,]" while the fifth patent was new and different because it concerned the "darkness of eyelashes." *Id.* at *2. The court disagreed. The court explained that the first four patents covered growing eyelashes *including* eyelashes that were long, thick and dark. *Id.* The court further noted that the fifth patent "repeatedly reference[d]" enhancing eyelash growth, just like the first four patents. *Id.* Accordingly, the relevant claims from the fifth patent were substantially similar to the claims from the first four patents, and the collateral estoppel barred further litigation. *Id.* at *2. The Federal Circuit affirmed, concluding that all of the litigation "concern[ed] eyelash darkness as well as broader qualities associated with hair growth[,]" and that the patent claims merely "use[d] slightly different language to describe

substantially the same invention[.]"[13] *Allergan*, 681 F. App'x at 961 (citation omitted).[14]

And a side-by-side comparison of the '793 and '782 Patents—which contain identical language throughout—and the alleged infringing activity here—which is identical to the alleged infringing activity in *Hatch-Waxman I* and *II*—confirms that UTC has identified no new infringing activity in this case. *See* Appendix A. Since the claims are substantially similar, all five collateral estoppel factors are met, and this Court should dismiss this action.

C. UTC's claims are precluded under the Federal Circuit's *Kessler* Doctrine.

UTC's claims are also precluded under the *Kessler* doctrine. *See Kessler v. Eldred*, 206 U.S. 285 (1907). Under that doctrine, UTC cannot re-accuse Yutrepia of infringing substantially the same patent claims that have already been found to be invalid.

"[U]nder *Kessler*, a party who obtains a final adjudication in its favor obtains 'the right to have that which it lawfully produces freely bought and sold without restraint or interference.'" *SpeedTrack, Inc. v. Office Depot, Inc.*, 791 F.3d 1317, 1323 (Fed. Cir. 2015) (quoting *Rubber Tire Wheel Co. v. Goodyear Tire & Rubber Co.*, 232 U.S. 413, 418

[13] The Federal Circuit reversed the district court's order invalidating the fifth asserted patent in its entirety. *Allergan*, 681 F. App'x at 963–64. Liquidia is not asking for such relief here, so that reversal is not relevant.

[14] *See also Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1319–20 (Fed. Cir. 2015) (holding that plaintiff was collaterally estopped from arguing infringement after the Federal Circuit found noninfringement in a parallel case); *Swartz v. United States Pat. & Trademark Off.*, 743 F. App'x 426, 427–28 (Fed. Cir. 2018) (holding that plaintiff's patent validity arguments were collaterally estopped based on previous Federal Circuit decisions invalidating similar patents).

(1914)). The Federal Circuit characterizes this as a "limited trade right" that "attaches to the product itself." *Id.* (citation omitted). The *Kessler* doctrine reflects "[t]he principle that, when an alleged infringer prevails in demonstrating noninfringement, the specific accused device(s) acquires the status of a noninfringing device vis-à-vis the asserted patent claims is an essential fact of a patent infringement claim." *Brain Life, LLC v. Elekta Inc.*, 746 F.3d 1045, 1057 (Fed. Cir. 2014) (cleaned up).

The right attaches after "an adjudication of non-liability for infringement[,]" whether based on non-infringement or invalidity, and whether or not a particular issue was "actually litigated." *In re PersonalWeb Techs.*, 961 F.3d at 1377, 1379. Thus, it can apply to claims that were voluntarily dismissed by the plaintiff where "the dismissal operated as an adjudication of non-liability for infringement[.]" *See id.* at 1379.

Kessler applies here because the final judgment from *Hatch-Waxman I* and UTC's dismissal of the '793 Patent in *Hatch-Waxman II*, protects Yutrepia from serial accusations that it infringes UTC's patents in identical ways. As Liquidia has explained, UTC does not allege that anything has changed about Yutrepia since *Hatch-Waxman I* was decided or since UTC's '793 Patent infringement allegations were dismissed from *Hatch-Waxman II*—not the product, delivery device, dosage, administration, or timing of subsequent doses.

Because the *Kessler* doctrine prohibits the "repeated harassment" of serial patent suits brought against the same noninfringing device, it prohibits this case. *In re PersonalWeb Techs.*, 961 F.3d at 1376 (citation omitted); *see also SimpleAir*, 884 F.3d at 1170 *(Kessler* doctrine, like claim preclusion, applies to patent claims that are not

patentably distinct from those previously litigated).

CONCLUSION

Liquidia requests the Court dismiss this case or, in the alternative, stay or transfer.

This the 15th day of May, 2025.

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CERTIFICATION OF COMPLIANCE

Pursuant to Local Rule 7.3(d)(1), the undersigned hereby certifies that this brief contains no more than 6,250 words, as calculated by the word count feature of Microsoft Word, Office 365 ProPlus.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was electronically filed with the Clerk of the Court by using the CM/ECF System which will automatically send notice of the same addressed to the following::

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